UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

GILDA HAGAN-BROWN Plaintiff, v. ELI LILLY AND COMPANY, an Indiana corporation, Defendant.	CASE NO.: 1:14-CV-01614
JANINE ALI Plaintiff, v. ELI LILLY AND COMPANY, an Indiana corporation, Defendant.	CASE NO.: 1:14-CV-01615

DEFENDANT'S OPPOSITION TO PLAINTIFFS' MOTION TO COMPEL TWO 30(B)(6) DEPOSITIONS AND THE DEPOSITION OF TORKIL FREDBORG

PRELIMINARY STATEMENT

In their Motion to Compel Two 30(b)(6) Depositions and the Deposition of Torkil Fredborg, Plaintiffs Janine Ali and Gilda Hagan-Brown ask the Court to order Defendant Eli Lilly and Company ("Lilly") to produce witnesses for depositions on topics that have no meaningful relevance to any viable claim in this litigation. In seeking to depose a company representative and Mr. Fredborg on Lilly's interactions with regulatory authorities in foreign countries, Plaintiffs seek information, including information on foreign medicine labeling, that numerous courts have held is not relevant in U.S.-based product liability litigation. In seeking to depose a corporate witness on the design of the Cymbalta capsule, Plaintiffs aim to take discovery on non-viable design defect claims that are necessarily preempted by federal law and on which Lilly has moved for judgment on the pleadings.

On top of the lack of any cognizable relevance, Plaintiffs' request also ignores the fact that the discovery already provided — including the foreign labels themselves and extensive deposition and documentary evidence about interactions concerning the foreign labeling — more than adequately satisfies any legitimate discovery need. The stated basis for this far-flung discovery — the need to investigate Lilly's knowledge and the adequacy of Cymbalta's labeling — has barely any nexus to the discovery sought, and the evidence most relevant to those questions (the extensive worldwide clinical data, worldwide adverse event reports, and scientific reports) has indisputably already been provided.

Because the factual matters Plaintiffs seek to explore in their proposed depositions are both irrelevant and duplicative, the Court should deny Plaintiffs' motion in its entirety. It would be both unjust and inefficient — requiring that lawyers be dispatched off to Europe to investigate and prepare witnesses for these irrelevant topics — to require Lilly to produce witnesses that would play no role in moving these two cases forward on the current accelerated schedule.

BACKGROUND

On March 24, 2015, Plaintiffs issued a notice in which they expressed their intention to take testimony of Lilly corporate witnesses pursuant to Federal Rule of Civil Procedure 30(b)(6) on four broad topics. *See generally* Pls.' Notice to Take Videotaped Oral Dep. Pursuant to Rule 30(b)(6), Mar. 24, 2015, Ex. 1 to the Declaration of Jeffrey T. Bozman ("Bozman Decl."). Lilly agreed to provide a witness to cover one of the topics ("Clinical Trials"), subject to working out more specific parameters to allow suitable preparation, and Plaintiffs withdrew one of the topics ("WebMD"). *See id.* at 3-4, 5. Lilly objected to the two remaining topics: "European Labeling for Cymbalta" and "the Cymbalta Capsule." *See id.* at 4-6. The sub-topics listed under the "European Labeling" heading focused exclusively on matters pertaining to Cymbalta's European label and Lilly's interactions with European regulatory authorities, including the European Medicines Agency. *See id.* at 4-5. The sub-topics listed under the "Cymbalta Capsule" heading focused exclusively on matters pertaining to Plaintiffs' design defect claims, which involve allegations that Lilly should have designed and distributed Cymbalta in capsules containing smaller doses or in a tablet or liquid form. *See id.* at 5-6; *see also Ali* Complaint, Dkt. No. 1, ¶¶ 19, 24, 48-49 (design defect allegations); *Hagan-Brown* Complaint, Dkt. No. 1, ¶¶ 19, 24, 48-49 (same).

On the issue of foreign labeling, Lilly explained that, pursuant to a well-established line of case authority, matters pertaining to foreign medicine labeling are irrelevant in a product liability lawsuit involving prescriptions, ingestion, and alleged injury in the United States. *See* E-mail from B. Stekloff to R. Brent Wisner, Apr. 3, 2015, Bozman Decl. Ex. 2 (citing *In re Seroquel Prods. Liab. Litig.*, 2009 WL 223140, at *6 (M.D. Fla. Jan. 30, 2009) & *In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d 950, 965 (D. Minn. 2009)). As for the Cymbalta capsule topic, Lilly explained that Plaintiffs' design defect claims are preempted by federal law pursuant

to United States Supreme Court precedent, and that discovery on matters pertaining to those claims would therefore be inappropriate. *See id.* Notably, Lilly has sought dismissal of Plaintiffs' design defect claims in a motion for judgment on the pleadings now pending before Judge Trenga. *See generally* Def.'s Mot. for J. on the Pleadings and Mem. of Law in Supp., Apr. 10, 2015, Dkt. Nos. 51 (*Hagan-Brown*) & 56 (*Ali*).

In addition to their 30(b)(6) deposition notice, Plaintiffs separately noticed the deposition of Mr. Torkil Fredborg, a Lilly employee based in the United Kingdom. *See* Pls.' Notice of Dep. of Torkil Fredborg, Mar. 23, 2015, Bozman Decl. Ex. 3. As Plaintiffs concede in their motion to compel, Mr. Fredborg's work on Cymbalta focused almost exclusively on European regulatory and labeling matters. *See* Pls.' Mem. at 15-17. For this reason, Lilly objected to the deposition on relevance grounds, just as it objected to Plaintiffs' efforts to take Rule 30(b)(6) testimony on irrelevant European labeling. *See* E-mail from B. Stekloff to R. Brent Wisner, Apr. 8, 2015, Bozman Decl. Ex. 4.

After the parties reached an impasse on these issues, Plaintiffs indicated they would file a motion to compel Rule 30(b)(6) depositions on European labeling and the Cymbalta capsule, as well as Mr. Fredborg's deposition. *See* E-mail from R. Brent Wisner to B. Stekloff, Apr. 8, 2015, Bozman Decl. Ex. 5. Plaintiffs filed their motion on April 10, 2015.

In their motion, Plaintiffs argue that the information sought, including information pertaining to foreign labeling and Cymbalta's capsule, will lead to evidence of Lilly's knowledge of alleged Cymbalta risks, how the company evaluated such risks, and whether Lilly's labeling for Cymbalta was adequate. *See* Pls.' Mem. at 9, 14-15. As a threshold matter, none of these justifications support the scope of foreign discovery sought here. The extensive evidence relevant to the issues — Lilly's worldwide clinical data, worldwide adverse event data, and

worldwide Periodic Safety Update Reports ("PSURs") — has already been provided, and Plaintiffs have taken significant discovery on these issues. For instance:

- Depositions of multiple key witnesses, including:
    - Dr. David Perahia. Medical Fellow in Lilly's Global Patient Safety function, lead author of "Symptoms Following Abrupt Discontinuation of Duloxetine Treatment in Patients with Major Depressive Disorder," Journal of Affective Disorders 89 (2005) 207-212, the primary manuscript discussing discontinuation symptoms in Lilly's Major Depressive Disorder trials, and author of more than twenty additional publications on Cymbalta. Bozman Decl. Ex. 6 (Perahia deposition excerpts); Bozman Decl. Ex. 7 (journal article); Declaration of Emily S. Ullman ("Ullman Decl.") ¶ 11.
    - Dr. Sharon Hoog. Longtime Lilly Medical Advisor who acted as liaison with the FDA regarding Cymbalta clinical study findings and who took part in the initial creation of the Cymbalta label. Bozman Decl. Ex. 8; Ullman Decl. ¶ 12.
    - Sara Mescher. Regulatory labeling consultant who was charged with managing and leading the creation and update of Cymbalta labeling within Lilly's Global Operations and Labeling Department. Bozman Decl. Ex. 9; Ullman Decl. ¶ 13.
    - Three 30(b)(6) witnesses covering key topics. Dr. Steven Knowles, Senior Medical Director in Global Patient Safety (drug safety), Bozman Decl. Ex. 10; Christine Phillips, Advisor in Global Regulatory Affairs (regulatory matters), Bozman Decl. Ex. 11; Elyas Musleh, Director of Learning Strategy (sales training), Bozman Decl. Ex. 12; Ullman Decl. ¶ 10.
- Production of e-mails of key Cymbalta employees in response to Plaintiffs' requests, including Nayan Acharya, Mark Bangs, Bryan Boggs, Greg Brophy, Sharon Hoog, and Anne Sakai-Robbins, all of whom were Lilly employees who played a significant role in, or were responsible for the creation and updates of, Cymbalta's U.S. label. Lilly also produced e-mails of Sara Mescher, a regulatory labeling consultant, and Michael Detke, a Cymbalta clinical research physician. Ullman Decl. ¶¶ 8-9.
- Lilly's IND/NDA files for Cymbalta, produced in response to Plaintiffs' requests for production, which include Lilly's submissions to, and correspondence with, FDA on labeling issues. *See* Ullman Decl. ¶¶ 2, 5.
- Full clinical trial reports for Cymbalta, produced in response to Plaintiffs' requests for production, which show Lilly's knowledge of adverse events revealed in clinical trials. *See* Ullman Decl. ¶ 3.
- 15,781 MedWatch adverse event reports, produced in response to Plaintiffs' requests for production, by which Lilly became aware of post-marketing reports of adverse events possibly related to Cymbalta. *See* Ullman Decl. ¶ 4.

And, to be sure, Plaintiffs already have significant discovery on the issue of foreign labeling, including over 400 foreign labels from countries around the world. *See* CYM-02778631 to CYM-02779583, Ullman Decl. ¶ 6 (foreign labels production). Apart from the labels, Lilly has provided the Periodic Safety Update Reports ("PSURs") for Cymbalta, which are the key periodic safety summaries sent to worldwide regulatory authorities. Ullman Decl. ¶ 5. These PSURs describe worldwide safety experiences and discuss major labeling changes over the reporting period. Lilly's production also includes examples of Risk Management Plans, which are European regulatory submissions that include information on a medicine's safety profile and how its risks will be prevented or minimized in patients. Ullman Decl. ¶ 10. Plaintiffs questioned Dr. Hoog about some of these submissions. *See* Deposition of Sharon L. Hoog, M.D. (Dec. 10, 2014), Bozman Decl. Ex. 8, at 152:8-167:13. Moreover, Plaintiffs have questioned several witnesses about the European labeling already, and, given the miniscule relevance this information will have, Plaintiffs cannot persuasively argue that they need still more information on such a tangential issue. *See, e.g.*, Deposition of Sara A. Mescher (Dec. 9, 2014), Bozman Decl. Ex. 9, at 49:24-55:10, 57:23-77:17, 109:3-25 (testimony on European label and its comparison to U.S. label), 142:6-146:7 (testimony on conceptual labeling consistency across countries and Cymbalta's core data sheet); Deposition of Sharon L. Hoog, M.D. (Dec. 10, 2014), Bozman Decl. Ex. 8, at 152:4-167:13, 177:24-185:7, 331:20-335:14, 351:10-355:12 (testimony on European regulatory submissions, European label, and European label's comparison to U.S. label); Deposition of Dr. David Perahia (Dec. 12, 2014), Bozman Decl. Ex. 6, at 160:23-162:24, 244:24-245:23 (testimony on European label and its comparison to U.S. label), 186:6-191:8, 194:19-202:4, 287:6-288:8, 300:13-302:7 (testimony on other global regulatory and medical documents).

Accordingly, in light of the voluminous discovery that has already been taken — and that will continue to be taken — on Cymbalta's possible risks, Lilly's knowledge of those risks, and Cymbalta's labeling, Plaintiffs' additional proposed testimony would be unnecessarily cumulative and duplicative even if it were relevant to those issues at all (which it is not).

LEGAL STANDARD

Although broad discovery of *relevant* matters is generally permitted, *see* Fed. R. Civ. P. 26(b)(1), discovery under the Federal Rules of Civil Procedure is not unlimited. Indeed, discovery is not appropriate where the information sought is not relevant to a party's claim or defense or where the discovery is not "reasonably calculated to lead to the discovery of admissible evidence." *Id.*; *see also WLR Foods, Inc. v. Tyson Foods, Inc.*, 65 F.3d 1172, 1183-87 (4th Cir. 1995) (affirming denial of discovery where information sought was not relevant and discovery was thus not "reasonably calculated to lead to the discovery of admissible evidence").

Moreover, even where the information sought might have some relevance to the claims of the party seeking discovery, the proposed discovery may nevertheless be inappropriate. *See Nicholas v. Wyndham Int'l, Inc.*, 373 F.3d 537, 543 (4th Cir. 2004) ("Even assuming that this information is relevant (in the broadest sense), the simple fact that requested information is discoverable under Rule 26(a) does not mean that discovery must be had."). Indeed, limitations on discovery are appropriate when the discovery sought would be unnecessarily cumulative, duplicative, or not proportional to the subject matter of the lawsuit:

> [A] district court may limit the frequency or extent of use of the discovery methods otherwise permitted under the Federal Rules of Civil Procedure if it concludes that (i) the discovery sought is unreasonably cumulative or duplicative, or is obtainable from some other source that is more convenient, less burdensome, or less expensive; (ii) the party seeking discovery has had ample opportunity by discovery in the action to obtain the information sought; or (iii) the burden or expense of the proposed discovery outweighs its likely benefit.

Id. (quoting Fed. R. Civ. P. 26(b)(2)).

A district court is also empowered to "make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, including an order that the discovery not be had." *Id.* (quoting Fed. R. Civ. P. 26(c) and holding that "the district court was well within its discretion to conclude that the additional discovery sought by Wyndham [under Rule 30(b)(6)] was cumulative and duplicative, unduly burdensome, and harassing").

LEGAL ARGUMENT

I. Because Foreign Regulatory Standards Are Irrelevant, Testimony Concerning Foreign Labeling Is Not Reasonably Calculated to Lead to the Discovery of Admissible Evidence.

Plaintiffs' proposed Rule 30(b)(6) deposition on foreign labeling issues would be inappropriate for two principal reasons. First, because foreign regulatory standards are irrelevant in this U.S.-based litigation, the proposed deposition testimony is not "reasonably calculated to lead to the discovery of admissible evidence." Fed. R. Civ. P. 26(b)(1). Second, the proposed discovery would be unjustifiably duplicative since Plaintiffs have already had ample opportunity — and will continue to have such opportunity — to obtain evidence pertaining to Lilly's knowledge of alleged Cymbalta risks, how the company evaluated such risks, and whether Lilly's U.S. labeling for Cymbalta was adequate.

A. Foreign Regulatory Standards and Labeling Are Irrelevant.

There is no dispute that these cases involve U.S.-based Plaintiffs who were prescribed Cymbalta by physicians based in the United States, who ingested Cymbalta in the United States, and who allegedly incurred injuries in the United States after taking the medicine. Nor is there any dispute that Cymbalta and its labeling were approved by the United States Food and Drug Administration ("FDA"), and that the FDA's regulatory standards — and *only* those standards — governed the initial approval and ongoing safety review of Cymbalta, including approval of the

labeling in effect at the time Plaintiffs ingested the medicine. Given these facts, evidence of the regulatory standards, regulatory decisions, and/or labeling of foreign countries has no relevance to Plaintiffs' claims in these cases.

As numerous courts have recognized, each country has its own distinct regulatory standards that "reflect the unique balance struck between the benefit each market derives from the product's use and the risks associated with that use; between the community's particular need for the product and its desire to protect its citizens from what it deems unreasonable risk." *Doe v. Hyland Therapeutics Div.*, 807 F. Supp. 1117, 1129 (S.D.N.Y. 1992). For this reason, the regulatory review process that governs the approval and ongoing safety review of a medicine will differ from country to country, as will the medicine labeling that results from that process. In short, every nation makes its own determinations regarding a pharmaceutical product (and its labeling) based on that nation's unique needs and interests. *See, e.g.*, *In re Fosamax Prods. Liab. Litig.*, 2009 WL 3398930, at *4 (S.D.N.Y. Oct. 21, 2009) ("[T]he foreign country in which the product was sold and ingested has the foremost interest in defining the standard of conduct which pharmaceutical companies must follow in distributing products under its regulatory scheme."); *Doe*, 807 F. Supp. at 1129 ("The forum whose market consumes the product must make its own determination as to the levels of safety and care required. That forum has a distinctive interest in explicating the controlling standards of behavior, and in enforcing its regulatory scheme."); *Harrison v. Wyeth Labs.*, 510 F. Supp. 1, 4 (E.D. Pa. 1980) ("Each country has its own legitimate concerns and its own unique needs which must be factored into its process of weighing the drug's merits, and which will tip the balance for it one way or the other.").

Given that each country imposes its own unique regulatory standards and labeling requirements when it reviews the safety and efficacy of a medicine, the regulatory review

process of a foreign nation has no bearing on the principal question presented in these cases: that is, whether Cymbalta's FDA-approved labeling was adequate to warn Plaintiffs' U.S.-based physicians of the potential symptoms that might occur when the medicine is discontinued. This rule — that foreign regulatory standards, regulatory decisions, and medicine labeling are irrelevant and inadmissible in U.S.-based product liability litigation — is widely recognized by courts. Indeed, this is the majority rule. *See, e.g., Meridia Prods. Liab. Litig. v. Abbott Labs.*, 447 F.3d 861, 867 (6th Cir. 2006) (holding that foreign medicine label created no "triable issue of fact" on question of adequacy of U.S. label); *In re Seroquel Prods. Liab. Litig.*, 2009 WL 223140, at *6 (M.D. Fla. Jan. 30, 2009) (holding that "foreign [prescription] labels and . . . foreign regulatory actions have no relevance" in product liability action concerning medicine and labels created under U.S. regulatory standards), *aff'd*, 601 F. Supp. 2d 1313 (M.D. Fla. 2009); *In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d 950, 965 (D. Minn. 2009) ("The Court finds that any discussion of foreign regulatory actions is irrelevant to the current litigation and should therefore be excluded."); *Zammit v. Shire US, Inc.*, 415 F. Supp. 2d 760, 767 n.6 (E.D. Mich. 2006) (concluding that regulatory decisions of other governments are "simply irrelevant") (applying Michigan law).[1]

[1] *See also, e.g., Hogan v. Novartis Pharms. Corp.*, 2011 WL 1533467, at *13 (E.D.N.Y. Apr. 24, 2011) ("I do not see the relevance of foreign regulatory actions and materials."); *In re Trasylol Prods. Liab. Litig.*, 709 F. Supp. 2d 1323, 1336 (S.D. Fla. 2010) (concluding that experts "should not be allowed to opine on foreign regulatory matters"); *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1054 (D. Minn. 2007) ("[T]he Court finds that allowing the admission of evidence of foreign regulatory actions, in a case that is governed by domestic law, would likely cause jury confusion. Given that notice is not dependent on governmental action, and to avoid jury confusion, the Court finds [plaintiff's expert's] testimony concerning foreign regulatory actions must be excluded."); *cf. In re Vioxx Prods. Liab. Litig.*, 448 F. Supp. 2d 741, 748 (E.D. La. 2006) ("An American jury would also have no good means of evaluating whether a given foreign label or marketing scheme was adequate[.]").

Notably, Judge Sweet recently recognized this rule in this very litigation, when a Cymbalta plaintiff unsuccessfully sought reconsideration of the Judge's ruling that Cymbalta's FDA-approved warnings were adequate as a matter of law. In seeking reconsideration, the plaintiff argued that an expert report addressing differences between the European and U.S. labels for Cymbalta was informative on the adequacy question. But Judge Sweet easily rejected this assertion, noting that European labeling is not instructive on the question of the adequacy of the U.S. warnings. *See McDowell v. Eli Lilly & Co.*, 2015 WL 845720, at *5 (S.D.N.Y. 2015) ("The mere existence of a differently structured and written European label does not establish that the U.S. label is insufficient, misleading, or legally inadequate, nor is foreign regulatory action even appropriate as a subject of expert testimony in pharmaceutical cases."). The same conclusion is required in these factually indistinguishable Cymbalta cases: foreign regulatory matters have no relevance to the adequacy of the FDA-approved warnings issued to Plaintiffs' U.S.-based physicians.[2]

Plaintiffs' efforts to elicit Rule 30(b)(6) testimony on foreign regulatory matters reflect a frequently attempted — but rarely permitted — effort by pharmaceutical plaintiffs to impugn a

[2] The cases Plaintiffs cite on the foreign labeling issue, *see* Pls.' Mem. at 7-9, involved different issues that simply do not apply here. None of the cases Plaintiffs cite involved an effort to obtain broad Rule 30(b)(6) testimony on an issue that had already been addressed through other discovery, and some involved situations in which the plaintiffs, unlike Plaintiffs here, had not already obtained foreign medicine labels through other discovery. *See Schedin v. Ortho-McNeil-Janssen Pharms., Inc.*, 808 F. Supp. 2d 1125, 1138-39 (D. Minn. 2011) (rejecting defendant's post-trial argument that evidence of foreign regulatory action was improper where defendant itself introduced such evidence at trial); *In re Yasmin & YAZ*, 2011 WL 6302287, at *27-28 (S.D. Ill. Dec. 16, 2011) (addressing expert testimony on foreign events); *Hardy v. Pharmacia Corp.*, 2011 WL 2118983, at *2-3 (M.D. Ga. May 27, 2011) (addressing situation in which plaintiffs, unlike Plaintiffs here, had not already received foreign labeling from defendants); *In re Levaquin Prods. Liab. Litig.*, 2010 WL 4676973, at *4-5 (D. Minn. Nov. 9, 2010) (permitting use of foreign regulatory evidence where, unlike here, other evidence of notice of risks apparently did not exist); *Estate of Tobin v. Smithkline Beecham Pharms.*, 2001 WL 36102165, at *1-2 (D. Wyo. May 18, 2001) (addressing use of foreign label documents at trial).

U.S. label by pointing to irrelevant differences in labels approved by different nations applying their own unique standards. Because Plaintiffs' proposed deposition topics are not "reasonably calculated to lead to the discovery of admissible evidence," *see* Fed. R. Civ. P. 26(b)(1), the discovery that Plaintiffs seek is improper and should not be permitted. *See WLR Foods, Inc. v. Tyson Foods, Inc.*, 65 F.3d 1172, 1183-87 (4th Cir. 1995) (affirming denial of discovery where information sought was not relevant and discovery was thus not "reasonably calculated to lead to the discovery of admissible evidence").

B. Plaintiffs' Proposed Deposition Would Be Unnecessarily Cumulative and Duplicative.

Plaintiffs attempt to overcome their relevance problem by claiming that discovery concerning foreign labeling might reveal what Lilly knew about "potential risks" or the actions it took to evaluate such risks. *See* Pls.' Mem. at 9. But Plaintiffs fail to explain how foreign labeling — which has no bearing on whether U.S. warnings were adequate — would illuminate those issues. Other courts have rightly rejected this same unfounded notice argument. *See, e.g.*, *In re Seroquel*, 2009 WL 223140, at *5-6 (rejecting plaintiffs' argument that "foreign labeling and regulatory actions . . . demonstrate [the defendant's] notice and knowledge of serious hazards reasonably associated with [the medicine] and are relevant to their allegations"); *In re Baycol*, 532 F. Supp. 2d at 1054 (rejecting notice argument and excluding evidence of foreign regulatory actions).

Moreover, Plaintiffs have already had ample opportunity, and will continue to have such opportunity, to explore Lilly's knowledge of alleged risks of Cymbalta through voluminous document discovery and depositions of several corporate witnesses. *See, e.g.*, CYM-01026706, CYM-01028897, CYM-01030818, CYM-01033964, CYM-01054242, CYM-01057305, CYM-01059490, CYM-01142733, CYM-01143897, CYM-01151177, CYM-01189297, CYM-

01191333, CYM-01212296, CYM-01213266, CYM-01215476, CYM-01220120, CYM-01221307, CYM-01491447, CYM-01493802, CYM-00183824, CYM-00186881, CYM-00189878, CYM-00191636, Ullman Decl. ¶ 3 (reports of Lilly's worldwide clinical trials related to Cymbalta, including adverse events revealed in each, all produced in response to Plaintiffs' document requests); CYM-01965712-CYM-01965865, CYM-01968151-CYM01968178, CYM-02382778-CYM-02382799, CYM-02382963-CYM-02382990, CYM-02388851-CYM-02388910, Ullman Decl. ¶ 7 (records of Lilly's Periodic Safety Review Committee relating to discontinuation-emergent adverse events); 30(b)(6) Deposition of Steven Paul Knowles, M.D., Lilly's Senior Medical Director of Global Patient Safety, Bozman Decl. Ex. 10, at 20:20-27:7 (describing Lilly's postmarketing surveillance of adverse events worldwide); *id.* at 43:2-44:21 (describing Lilly's review of medical literature for adverse events); *id.* at 186:11-187:15 (describing Lilly's targeted surveillance for drug discontinuation adverse events); *id.* at 191:6-193:19 (describing adverse events associated with discontinuation identified by Lilly's drug safety surveillance function); *id.* at 197:18-205:2 (describing label's listing of adverse events revealed in worldwide clinical trials); 30(b)(6) Deposition of Elyas Musleh, Lilly's Sales Training Leader, Bozman Decl. Ex. 12, at 18:5-21:4, 57:9-58:10, 112:2-123:2 (describing Lilly's training of sales representatives for adverse event reporting). Among other things, Lilly has also identified for Plaintiffs a set of 15,871 MedWatch reports — all produced in response to Plaintiffs' document requests — reflecting worldwide adverse events related to discontinuation of Cymbalta in Lilly's possession. Ullman Decl. ¶ 4.

Exploration of the contents of foreign labeling and interactions with foreign regulatory authorities thus would not meaningfully expand the universe of relevant evidence, and therefore would only serve to harass Lilly. Indeed, the terms of the foreign labeling topic itself are so

broad as to be almost unanswerable without months of investigation and preparation.[3] The Court should reject Plaintiffs' efforts to engage in such unreasonable, cumulative discovery. *See, e.g.*, *Ingle v. Yelton*, 264 F. App'x 336, 339 (4th Cir. 2008) ("A district court must limit the frequency or extent of discovery . . . if it concludes that (i) the discovery sought is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive; (ii) the party seeking discovery has had ample opportunity to obtain the information by discovery in the action; or (iii) the burden or expense of the proposed discovery outweighs its likely benefit." (quoting Fed. R. Civ. P. 26(b)(2)(C))); *Nicholas v. Wyndham Int'l, Inc.*, 373 F.3d 537, 543 (4th Cir. 2004) (affirming district court's denial of litigant's efforts to take "cumulative and duplicative" 30(b)(6) testimony).[4]

II. Plaintiffs' Efforts to Depose Mr. Fredborg Are Merely an Effort to Obtain Back-Door Discovery on Foreign Labeling.

Plaintiffs' efforts to depose Torkil Fredborg, a European employee who played virtually no role in the development of the U.S. labeling, is nothing more than an attempt to obtain discovery of foreign labeling evidence through the back door. Plaintiffs essentially concede as much in their motion, in which they describe Mr. Fredborg's involvement in European labeling matters and acknowledge his minimal involvement in U.S. labeling issues. *See* Pls.' Mem. at 15

[3] Even according to Plaintiffs, they ingested Cymbalta for a matter of months and their symptoms improved within months of their respective discontinuations of the medicine. Plaintiffs' wide-ranging, overly broad discovery requests should be viewed in this light; Plaintiffs are litigating claims related to their specific use of Cymbalta, rather than the entire history of the drug.

[4] Plaintiffs note that the truth and accuracy of Cymbalta's European labeling has already been established via earlier discovery, *see* Pls.' Mem. at 1, 5-6, but this undermines their position more than it helps it. If Plaintiffs have already obtained access to Cymbalta's European labeling and established its truth and accuracy, then there is no need for intrusive Rule 30(b)(6) testimony on those issues.

("It appears that Mr. Fredborg played a key role in the development of the language in the European label dealing with withdrawal[.]"); *id.* at 16 ("[T]he e-mail indicates that Mr. Fredborg was instrumental in cultivating the language on the European label."). Because foreign labeling has no relevance in this litigation, a deposition of Mr. Fredborg would not be "reasonably calculated to lead to the discovery of admissible evidence." Fed. R. Civ. P. 26(b)(1); *see also WLR Foods*, 65 F.3d at 1183-87.

Moreover, a deposition of Mr. Fredborg would be unreasonably cumulative or duplicative since Plaintiffs have already deposed numerous company employees on labeling issues and admit that Lilly has produced, and will continue to produce, Mr. Fredborg's e-mails. *See* Pls.' Mem. at 3 ("Lilly has produced part of Mr. Fredborg's e-mails as they exist on Lilly's U.S. e-mail servers, and is in the process of producing Mr. Fredborg's remaining e-mails from Lilly's European servers."); *see also, e.g.*, Ullman Decl. ¶ 2 (describing production of 1.75 million pages from Lilly's United States regulatory IND/NDA files, including thousands of pages of FDA correspondence and submissions); Letter from Emily Ullman to T. Matthew Leckman at 2-3 (Nov. 11, 2014), Bozman Decl. Ex. 13 (agreeing to produce the e-mails of Lilly employees, including Nayan Acharya, Mark Bangs, Greg Brophy, Sharon Hoog, Bryan Boggs, and Anne Sakai-Robbins, all of whom were Lilly employees who played a significant role in, or were responsible for the creation and updates of, Cymbalta's U.S. label); Deposition of Sara A. Mescher (Dec. 9, 2014), Bozman Decl. Ex. 9, at 23:17-24:19 (discussing competitor labeling as related to Cymbalta label), 24:19-25:9 (discussing Lilly labeling standards), 30:3-39:12 (testifying on substance of Cymbalta discontinuation warning), 47:6-49:23 (testifying on consistency of medical literature with Cymbalta label), 57:10-64:11 (testifying on relationship between discontinuation warnings in U.S. label and European label); Deposition of Sharon L.

Hoog, M.D. (Dec. 10, 2014), Bozman Decl. Ex. 8, at 22:25-30:15 (testifying on Cymbalta label preparation process), 152:4-162:25 (testifying on European risk management plan submission, including labeling); 168:24-177:23 (testifying on discontinuation warning in U.S. label); Deposition of Christine Phillips, Ph.D. (July 18, 2014), Bozman Decl. Ex. 11, at 11:6-28:4, 38:3-40:13, 165:5-167:19 (30(b)(6) deposition on Lilly regulatory affairs).

Plaintiffs' lengthy recitation of documents involving Mr. Fredborg is telling: it demonstrates that they have already obtained considerable discovery concerning this peripheral witness, that Mr. Fredborg's involvement in U.S. issues was minimal, and that Plaintiffs will nevertheless continue to obtain discovery concerning Mr. Fredborg in a forthcoming e-mail production of his documents. *See* Pls. Mem. at 15-17. Plaintiffs' insistence that they must now obtain deposition testimony from this witness on irrelevant foreign labeling issues is untenable. The Court should deny Plaintiffs' efforts to engage in unnecessary discovery.

III. Discovery on the Cymbalta Capsule Would Be Inappropriate Because Plaintiffs' Design Defect Claims Are Preempted by Federal Law.

Plaintiffs' efforts to obtain Rule 30(b)(6) testimony on the design of the Cymbalta capsule also would be improper. As explained in detail in Lilly's motion for judgment on the pleadings, which is now pending before Judge Trenga and noticed for a hearing on May 1, 2015, Plaintiffs' design defect claims are not viable because, even if all of Plaintiffs' design-related allegations are true, those claims are necessarily preempted by federal law. Plaintiffs should not be permitted to take discovery on matters that pertain only to claims that fail as a matter of law.

The reasons why Plaintiffs' design defect claims are preempted by federal law are outlined in detail in Lilly's motion for judgment on the pleadings, which Lilly incorporates by reference here. *See generally* Def.'s Mot. for J. on the Pleadings and Mem. of Law in Supp., Apr. 10, 2015, Dkt. Nos. 51 (*Hagan-Brown*) & 56 (*Ali*). In summary, there are two principal

bases for preemption. *First*, there can be no question that Lilly could not unilaterally implement Plaintiffs' proposed alternative designs — that is, distribution of Cymbalta in capsules containing smaller doses or in a tablet or liquid form — without violating federal law. *See Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2470-71 (2013) (describing federal statutes and regulations that require prior FDA approval of medicine's formulation). *Second*, binding decisions of the United States Supreme Court demonstrate that, where a manufacturer could not implement a state-mandated design without a federal agency's prior approval, the state requirement must yield to federal law under principles of "impossibility preemption." *See PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2580-81 (2011) ("To decide these cases, it is enough to hold that when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for preemption purposes."); *Bartlett*, 133 S. Ct. at 2477 (holding that plaintiffs' state-law "design-defect cause of action is pre-empted with respect to FDA-approved drugs sold in interstate commerce" because "it is impossible for [defendant] and other similarly situated manufacturers to comply with both state and federal law"). In light of these precedents, Plaintiffs' claims that state law required a different formulation of Cymbalta are "without effect." *Bartlett*, 133 S. Ct. at 2477.

In an apparent effort to circumvent these binding Supreme Court decisions, Plaintiffs predictably point to the Supreme Court's decision in *Wyeth v. Levine*, 555 U.S. 555 (2009), to argue that the Supreme Court's preemption jurisprudence applies only to generic manufacturers, and not to brand-name manufacturers. *See* Pls.' Mem. at 13-14 & n.5. However, as Lilly explains in detail in its motion for judgment on the pleadings, this unprincipled interpretation of *Levine* is contrary to the plain language of the *Levine*, *Mensing*, and *Bartlett* decisions and has

been rejected by numerous lower courts for that reason. *See Bartlett*, 133 S. Ct. at 2479 ("Once a drug — *whether generic or brand-name* — is approved, the manufacturer is prohibited from making any major changes to the qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application.") (emphasis added) (quotation marks omitted); *see also Yates v. Ortho-McNeil Pharm., Inc.*, — F. Supp. 3d —, 2015 WL 66423, at *5-7 (N.D. Ohio 2015) (relying on *Bartlett* to conclude that design defect claim against manufacturer of brand-name birth control patch was preempted: "Although Ms. Yates' attorneys assert that the preemption is applicable to only generic drugs, the language in *Bartlett* and *Amos* is not so restrictive."); *Booker v. Johnson & Johnson*, — F. Supp. 3d —, 2014 WL 5113305, at *2, *4-5 (N.D. Ohio 2014) (relying on *Bartlett* to conclude that design defect claim against manufacturer of brand-name birth control patch was preempted); *Amos v. Biogen Idec Inc.*, 28 F. Supp. 3d 164, 169 (W.D.N.Y. 2014) (relying on *Bartlett* to conclude that design defect claims against manufacturer of brand-name multiple sclerosis medicine were preempted); *Thompson v. Allergan USA, Inc.*, 993 F. Supp. 2d 1007, 1013-14 (E.D. Mo. 2014) (relying on *Mensing* and *Bartlett* to find state-law claims preempted where plaintiffs alleged that manufacturer of brand-name prescription eye medication should have distributed medicine in vials containing smaller quantities). Indeed, Plaintiffs' attorney in these cases recently encountered this very outcome in a case decided by the First Circuit. *See In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 35, 40-43 (1st Cir. 2015) (rejecting *Levine*-based argument and relying on *Mensing* and *Bartlett* to hold that consumer fraud claims against brand-name manufacturer failed under principles of impossibility preemption: "The [Supreme] Court thus limited *Wyeth* [*v. Levine*] to situations in which the drug

manufacturer can, of its own volition, strengthen its label in compliance with its state tort duty.") (quotation marks omitted).

Plaintiffs also confusingly cite the *Saavedra* decision as support for their position on preemption. *See* Pls.' Mem. at 14. However, that decision did not consider — and issued no ruling on — preemption of design defect claims. *See Saavedra v. Eli Lilly & Co.*, 2013 WL 6345442, at *6-7 (C.D. Cal. Feb. 26, 2013) (addressing preemption issues unrelated to design defect claims).

Further, Plaintiffs appear to argue that discovery on theoretical alternative designs is appropriate because it is somehow relevant to: (1) alleged discontinuation side effects associated with Cymbalta as marketed, and/or (2) Plaintiffs' failure-to-warn claims. *See* Pls.' Mem. at 14-15. This suggestion is simply false. As explained *supra*, Plaintiffs have had ample opportunity, and will continue to have such opportunity, to obtain discovery on the alleged risks of the product as marketed and the contents of its labeling. Discovery on theoretical alternative product designs would have no bearing on these issues.

Finally, Plaintiffs suggest that the assertion of an affirmative defense like preemption can never constitute a basis for opposing discovery, but they tellingly cite no authority for this proposition. *See* Pls.' Mem. at 13. And, in any event, Lilly has done more than assert its defense: it has filed a motion for judgment on the pleadings seeking dismissal of Plaintiffs' design defect claims on preemption grounds. The non-viability of those claims necessarily extinguishes Plaintiffs' right to any discovery concerning factual matters — such as the design of the Cymbalta capsule — that uniquely pertain to those claims.

For these reasons, Rule 30(b)(6) deposition testimony on the design of the Cymbalta capsule cannot possibly "lead to discovery of admissible evidence" in support of a viable claim.

See Fed. R. Civ. P. 26(b)(1). This discovery issue is ripe for resolution now, but should the Court have any reservations on that point, Lilly respectfully submits that, at a very minimum, Lilly should not be ordered to produce a corporate witness on this issue until after the District Court rules on Lilly's pending motion for judgment on the pleadings.

CONCLUSION

For the foregoing reasons, the Court should deny Plaintiffs' motion to compel in its entirety.

Dated April 14, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the 14th day of April, 2015, I will electronically file the foregoing with the Clerk of the Court using the CM/ECF system, which will then send a notification of such filing (NEF) to the following:

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